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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,387	06/29/2000	BERND FABRY	H-3185-PCT/U	2050
23657	7590 09/20/2002			
	ORPORATION	EXAMINER		
	SSANCE BLVD., SUIT LS, PA 19406	E 200	JIANG, SHAOJIA A	
			ART UNIT	PAPER NUMBER
			1617	
			DATE MAILED: 09/20/2002 19	

Please find below and/or attached an Office communication concerning this application or proceeding.

,	Application No.	Applicant(s)				
Advisory Action	09/554,387	FABRY, BERND				
, turico, y riouon	Examiner	Art Unit				
	Shaojia A. Jiang	1617				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
THE REPLY FILED 21 August 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.						
PERIOD FOR REPLY [check either a) or b)]						
a) The period for reply expires 4 months from the mailing date of the final rejection.  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).  Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.						
2. The proposed amendment(s) will not be entered because:						
(a) they raise new issues that would require further consideration and/or search (see NOTE below);						
(b) they raise the issue of new matter (see Note below);						
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or						
(d) they present additional claims without canceling a corresponding number of finally rejected claims.  NOTE:						
3. Applicant's reply has overcome the following rejection(s):						
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).						
5.⊠ The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.						
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.						
7. For purposes of Appeal, the proposed amendment explanation of how the new or amended claims we						
The status of the claim(s) is (or will be) as follows:	_					
Claim(s) allowed: none.						
Claim(s) objected to: <u>none</u> .						
Claim(s) rejected: <u>11-30</u> .						
Claim(s) withdrawn from consideration: <u>none</u> .						
8. The proposed drawing correction filed on is a) approved or b) disapproved by the Examiner.						
9. Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s)						
		PRIMARY EXAMINER				
U.S. Patent and Trademark Office		1 1				

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## Advisory Action

This Office Action is a response to Applicant's amendment and response <u>after</u>

<u>FINAL</u> filed on August 21, 2002.

5. Applicant's remarks filed August 21, 2002 with respect to the rejection of claims 11-30 made under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939) and Hasegawa et al. in view of Miettinen et al. (EP 0594612B1), and Hidvegi (5,277,910) have been fully considered but are unpersuasive for reasons of record stated in the Final Office Action dated April 22, 2002.

Again, Applicant's arguments that the cited prior art does not teach or suggest to combine a phytosterol and a conjugated fatty acid have been considered but are not found persuasive.

As discussed clearly in the Final Rejection, Jandacek teaches <u>broadly</u> the usefulness of phytosterols such as  $\beta$ -sitostenol along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms <u>including</u> any conjugated fatty acids having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, in the instant claimed method. Moreover, Miettinen et al. teaches <u>broadly</u> the usefulness of fatty acids esters of  $\beta$ -sitosterol ( $\beta$ -sitostenol) and  $\beta$ -sitostanol containing approx. 2-22 carbon atoms and up to about 3 double bonds in the instant claimed method for reducing serum cholesterol content in a mammal, i.e., rapeseed oil is well known that rapeseed oil contains about 90% unsaturated fatty acids having one or more double bonds. Hasegawa's teaching that the particular fatty acid, linoleic acid, and/or phytosterol including sitosterol

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(sitostenol) are useful for lowering the serum cholesterol in human mammals provides further motivation for the instant method. Thus, the employment of a conjugated fatty acid herein is seen to be suggested by the prior art.

Moreover, as discussed in the Final Office Action, Applicant's data of Examples and Table 1 in the specification at pages 8-9 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive because the results from the test on the employment of  $\beta$ -sitostenol or  $\beta$ -sitostanol combined with conjugated linoleic acid in the composition do not show any additive effects on reducing the cholesterol content in rats after 12 hours. After 24 or 48 hours the results merely demonstrate less than additive therapeutic effects of β-sitostenol and conjugated linoleic acid in the composition on serum cholesterol levels in rats. Further, the specification provides no side-by-side comparison between the employment of unconjugated fatty acids and conjugated **fatty acids** with  $\beta$ -sitostenol or  $\beta$ -sitostanol in the claimed method herein. The comparison merely between the combination herein and a phytostenol compound or a conjugated fatty acid alone in the specification herein is insufficient to clearly demonstrate any possible unexpected supra additive effects for the combination over the cited prior art (i.e., the combination of unconjugated fatty acids with β-sitostenol or β-sitostanol in the claimed method). Moreover, the tests herein merely employ the combination of two particular phytostenols, β-sitostenol or β-sitostanol in combination with the particular conjugated fatty acid, conjugated linoleic acid. Thus, the evidence in the testing on is not commensurate in scope with the claimed invention and does not

demonstrate criticality of a claimed <u>range</u> of phytostenol compounds and conjugated fatty acids herein. See MPEP § 716.02(d). Therefore, the results herein are clearly expected and not unexpected based on the cited prior art.

Therefore, <u>no clear and convincing evidence</u> of nonobviousness or unexpected results for the combination in the claimed method presented in specification herein is seen to support the nonobviousness of the instant claimed invention over the prior art.

Therefore, motivation to combine the teachings of the prior art to make the present invention is seen and no impermissible hindsight is seen. The claimed invention is clearly obvious in view of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D. Patent Examiner, AU 1617 September 19, 2002

SREENI PADMANABHAN